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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,026	08/26/2003	Liqin Sun	998067 PA 1	3490
30781 PHILIP K. YU	7590 01/09/200 ²	EXAMINER		
20955 PATHF	INDER ROAD	VAKILI, ZOHREH		
SUITE 100 DIAMOND BA	AR, CA 91765	. ART UNIT	PAPER NUMBER	
	,	1614		
SHORTENED STATUTOR	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		01/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Applica	tion No.	Applicant(s)	Applicant(s)			
Office Action Summary			,026 .	SUN, LIQIN				
			er	Art Unit				
		Zohreh	Vakili	1614				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1) 🛛	Responsive to communication(s) file	ed on <i>04 November</i>	2006.					
·	,	2b)⊠ This action is			_			
·—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
,	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
4)🛛	4)⊠ Claim(s) <u>1-18</u> is/are pending in the application.							
4	4a) Of the above claim(s) <u>7-11,15,16 and 18</u> is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.								
6)⊠	6)⊠ Claim(s) <u>1-6,12-14 and 17</u> is/are rejected.							
7)🖂	7) Claim(s) <u>2-6, 14 and 17</u> is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.								
8) Claim(s) are subject to restriction and/or election requirement. Application Papers								
9) 🗌 -	The specification is objected to by th	e Examiner.		•				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority u	nder 35 U.S.C. § 119				·			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:								
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
•	3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
Attachment(s)								
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date								
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:								

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the restriction group I (claims 1-6, 12-14, & 17) filed on November 4, 2006 is acknowledged.

Claim Objection

Claims 2, 3, 4, 5, 6 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 14 is objected to because of the following informalities. The word "patent's" should be "patient's". Appropriate correction is required.

Çlaim 2 is objected to because of the following informalities. The word "releasabley" should be "releasably". Appropriate correction is required.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 3-6, 13, and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as extracts of Ligusticum, etc. which meet the written description and enablement provisions of 35 USC 112, first paragraph.

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However, claims 3-6, 13, and 17 are directed to encompass extracts, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these extracts, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

<u>Vas-Cath, Inc. v. Mahurkar</u>, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*. (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skiled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification

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provided only the bovine sequence. Finally, <u>University of California v. Eli Lilly and Co.</u>, 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood,* 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that <u>Vas-Cath</u> makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

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Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of what is meant by "releasabley affixed". The phrase may be misspelled, but either way, is not described in the Specification to the extent one of ordinary skill would understand in what way the protection layer is "affixed" to the pressure sensitive layer.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those

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skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Claims 1, 3-6, and 17 are vague and indefinite under 112, 2nd paragraph, due to lacking clarity in requiring whether or not those claims require that the claimed patch actually contains medication.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 12-14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by OCULAX™, copyright 3T Herbtech Inc. 2000.

The instantly claimed invention is apparently the commercial product OCULAX™ as described on page 6 of the instant specification and that the website printout is reasonable evidence of commercial availability on sale of the instant invention more than one year before disclosure as filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Konishi (US Patent No. 4858604).

Konishi in its invention teach an adhesive bandage comprising a pad for absorbing a medicine which is separately stored from the pad by means of a medicine covering film interposed between the medicine and the adhesive tape or by means of a capsule enclosing the medicine in it until the bandage is applied to a local site of body such as wound, an adhesive tape carrying the pad thereon, a release sheet provided with a blister portion adapted to placing the medicine in it and attached to the adhesive tape in such a manner that the open side of the blister may face the adhesive tape (see abstract). Konishi further teaches the invention comprises an adhesive tape carrying a pad, and a medicine enclosed in a space defined between a medicine covering film and a blister formed on a release sheet. The release sheet may be provided at one end with a slit along which the release sheet may be bent so that it may be easily removed. An appropriate quantity of the medicine is put into a blister formed at a predetermined position of the release sheet and the recess is sealed with the medicine covering film by the press trough pack method. Then, the release sheet is attached to the adhesive tape carrying a pad (see column 2, lines 23-41).

The above reference teaches a transdermal patch for releasing various kinds of medicines, a sterilizer, an anti-inflammatory agent, an anti-histamine. The patch consists of the adhesive tape, the pad, the release sheet, the blister for medicine storage, and when the bandage is to be applied to a wound, a finger pressure is applied to the blister to rupture the medicine covering film to cause the medicine to flow onto the

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pad. Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili Patent Examiner 1614/TC 1600 January 4, 2007

SUPERVISORY PATENT EXAMINER